

§ 21.45

the minor child or the incompetent individual, in addition to verifying his own identity, by providing a copy of the minor's birth certificate, a court order, or other evidence of guardianship.

(d) Where an individual seeks access to particularly sensitive records, such as medical records, the individual may be required to provide additional information beyond that specified in paragraph (b) or (c) of this section, such as the individual's years of attendance at a particular educational institution, rank attained in the uniformed services, date or place of birth, names of parents, an occupation, or the specific times the individual received medical treatment.

§ 21.45 Fees.

(a) Where applicable, fees for copying records shall be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual has requested that a copy be made of a record to which he is granted access. No fee may be charged for making a search of a Privacy Act Record System whether the search is manual, mechanical, or electronic. Where a copy of the record must be made to provide access to the record, e.g., computer printout where no screen reading is available, the copy shall be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual under § 21.33, no fee will be charged.

(b) The fee schedule is as follows:

(1) Copying of records susceptible to photocopying—\$.10 per page.

(2) Copying of records not susceptible to photocopying, e.g., punch cards or magnetic tapes—at actual cost to the determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying for an individual does not exceed \$25.

(c) When a fee is to be assessed, the individual shall be notified prior to the processing of the copies, and be given an opportunity to amend his request. Payment shall be made by check or money order made payable to the "Food and Drug Administration," and shall be sent to the Accounting Branch (HFA-120), Food and Drug Administra-

21 CFR Ch. I (4-1-03 Edition)

tion, 5600 Fishers Lane, Rockville, MD 20857. Advance deposit shall be required where the total amount exceeds \$50.

[42 FR 15626, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

Subpart E—Procedures for Requests for Amendment of Records

§ 21.50 Procedures for submitting requests for amendment of records.

(a) An individual who received access to a record about himself under subpart D of this part may request that the record be amended if he believes that the record or an item of information is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete.

(b) Amendments under this subpart shall not violate existing statute, regulation, or administrative procedure.

(1) This subpart does not permit alteration of evidence presented in the course of judicial proceedings or Food and Drug Administration adjudicatory or rule making proceedings or collateral attack upon that which has already been the subject of any such proceedings.

(2) If the accuracy, relevancy, timeliness, or completeness of the records may be contested in any other pending or imminent agency proceeding, the Food and Drug Administration may refer the individual to the other proceeding as the appropriate means to obtain relief. If the accuracy, relevance, timeliness, or completeness of a record is, or has been, an issue in another agency proceeding, the request under this section shall be disposed of in accordance with the decision in the other proceeding, absent unusual circumstances.

(c) Requests to amend records shall be submitted, in writing, to the FDA Privacy Act Coordinator in accordance with § 21.40(b). Such requests shall include information sufficient to enable the Food and Drug Administration to locate the record, a brief description of the items of information requested to be amended, and the reasons why the record should be amended together with any appropriate documentation or arguments in support of the requested